

### **REMARKS**

Claims 1 and 2 have been amended. No new matter has been added. Support for the claim amendments may be found throughout the specification.

Applicants thank the Examiner for withdrawing the previous objections to the disclosure and claims.

Claims 1, 2 and 5-16 are pending.

### **CLAIM REJECTIONS**

#### ***Rejection of claims under 35 U.S.C. 102(b)***

The Examiner has maintained the rejection of claims 1, 2, 4-8, 10 and 12-16 under 35 U.S.C. § 102(b) as being anticipated by Nishikawa et al. (*Development*, 1998; Vol. 125, p. 1747-1757) ("Nishikawa"). See Office Action at p. 3. Claim 4 was previously cancelled thus rendering this rejection moot with respect to claim 4. Claims 10 and 12-16 depend from independent claim 1 and 2.

With respect to Applicants' previous arguments concerning the phrase "repeating steps (b)-(c) iteratively as required," the Examiner contends that the phrase "as required" implies that the step "may or may not be required as 'as required' is defined as according to need or as needed." See Office Action at p. 4. Applicants respectfully traverse this rejection. Not in acquiescence to the rejection but in an effort to expedite prosecution, Applicants have amended claims 1 and 2 to delete the phrase "as required" in step (d).

Nishikawa describes that "CCE ES cells ... were initially maintained in Mitomycin C ... treated embryonic fibroblast layers in Dulbecco modified essential medium (DMEM: Gibco) ...." See p. 1748. Nishikawa further describes transferring ES cells "to gelatin (Sigma, USA)-coated culture dishes to remove fibroblasts." *Id.* Nishikawa also states that "10<sup>4</sup> ES cells were then transferred to each well of type IV collagen-coated 6-well cluster dishes ... and incubated in a-MEM supplemented with 10% FCS and 5X10<sup>-5</sup>M 2ME." *Id.* Nishikawa then describes harvesting the cells. *Id.* Nishikawa does not describe a method for determining the effect of a plurality of culture conditions on a cell that includes the steps of: (a) providing a first set of groups of cell units each including one or more cells, and exposing the groups to desired culture conditions, (b) subdividing one or more of the groups to create a further set of groups of cell units, (c) exposing the further groups to further desired culture conditions, (d) repeating steps

(b)-(c) iteratively and (e) assessing the effect on a given cell unit of the culture conditions to which it has been exposed. Nishikawa also does not describe a method for determining the effect of a plurality of culture conditions on a cell, that includes the steps of a) providing a first set of groups of cell units each including one or more cells, and exposing the groups to desired culture conditions, (b) pooling two or more of the groups to form at least one second pool, (c) subdividing the second pool to create a further set of groups of cell units, (d) exposing said further groups to desired culture conditions, (e) repeating steps (b)-(d) iteratively and (f) assessing the effect on a given cell unit of the culture conditions to which it has been exposed.

Since Nishikawa does not describe that the split-split or pool-split steps are repeated as described in claims 1 and 2, dependent claim 10 and 12-16 should be patentable over Nishikawa for at least the same reasons described above. Applicants respectfully request reconsideration and the withdrawal of this rejection.

***Rejection of claims under 35 U.S.C. 102(e)***

The Examiner has maintained the rejection of claims 1, 2 and 4-16 under 35 U.S.C. § 102(e) as being anticipated by U.S. Publication No. 2004/0170965 to Scholl et al. ("Scholl"). See Office Action at p. 5. Claim 4 was previously cancelled thus rendering this rejection moot with respect to claim 4. Claims 10 and 12-16 depend from independent claim 1 and 2.

With respect to Applicants' previous arguments concerning the phrase "repeating steps (b)-(c) iteratively as required," the Examiner contends that the phrase "as required" implies that the step "may or may not be required as 'as required' is defined as according to need or as needed." See Office Action at p. 6. Applicants respectfully traverse this rejection. Not in acquiescence to the rejection but in an effort to expedite prosecution, Applicants have amended claims 1 and 2 to delete the phrase "as required" in step (d).

Scholl describes that [c]ells to be cultured were harvested by first rinsing source cell monolayers with Hank's Balanced Salt Solution (HBSS) without magnesium or calcium." See paragraph [149] of Scholl. Scholl further describes that "[d]epending upon the cell line, the cells were dissociated by adding trypsin ... or trypsin-EDTA" and adding cell culture medium to the trypsinized cell suspension. *Id.* Scholl also describes diluting the trypsinized cell suspension "to produce an optical density of cell suspension suitable to produce a confluent monolayer of cells within 2-3 days of incubation in a 96-well microtiter plate." *Id.* Accordingly, Scholl does not

describe a method for determining the effect of a plurality of culture conditions on a cell that includes the steps of: (a) providing a first set of groups of cell units each including one or more cells, and exposing the groups to desired culture conditions, (b) subdividing one or more of the groups to create a further set of groups of cell units, (c) exposing the further groups to further desired culture conditions, (d) repeating steps (b)-(c) iteratively and (e) assessing the effect on a given cell unit of the culture conditions to which it has been exposed. Scholl also does not describe a method for determining the effect of a plurality of culture conditions on a cell, that includes the steps of a) providing a first set of groups of cell units each including one or more cells, and exposing the groups to desired culture conditions, (b) pooling two or more of the groups to form at least one second pool, (c) subdividing the second pool to create a further set of groups of cell units, (d) exposing said further groups to desired culture conditions, (e) repeating steps (b)-(d) iteratively and (f) assessing the effect on a given cell unit of the culture conditions to which it has been exposed.

Since Scholl does not describe that the split-split or pool-split steps are repeated as described in claims 1 and 2, dependent claim 10 and 12-16 should be patentable over Scholl for at least the same reasons described above. Applicants respectfully request reconsideration and the withdrawal of this rejection.

### CONCLUSION

Applicant believes that the claims are in condition for allowance. Should any fees be required by the present Reply, the Commissioner is hereby authorized to charge Deposit Account 19-4293.

Respectfully submitted,

Date: 7-10-09

**Customer No. 27890**  
Steptoe & Johnson LLP  
1330 Connecticut Avenue, NW  
Washington, DC 20036-1795  
Phone: 202-429-6748  
Fax: 202-429-3902



Harold H. Fox  
Reg. No. 41,498